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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,959	10/24/2003	Ratan K. Chaudhuri	EMI-55	6979

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EXAMINER

LEITH, PATRICIA A

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,959

Applicant(s)

CHAUDHURI, RATAN K.

Examiner

Patricia Leith

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-13,17-24 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 9-13 and 17-24 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

HL

S.O.O

DETAILED ACTION

Claims 1, 9-13 and 17-24 and 28-30 are pending in the application, claims 28-30 being newly added in the most recent amendment filed 4/11/05.

All claims were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Priority

Applicant has indicated that this application is a CIP of 10/616,299 however, Applicant still fails to perfect domestic priority because there is no specific statement stating the relationship between this application and US 6,124,268 or application number 10/660,742. The Examiner cannot clearly understand what type of relationship this case has with the above cited cases, and therefore cannot determine if priority exists back to the effective filing of these cases. Applicant is asked to specifically state how each utility case is related to each other in order to perfect a case for domestic priority.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New claims 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claims 28-30 now recite 'wherein the sunscreen comprises said standardized extract'. This information cannot be found in the original Disclosure as filed; explicitly nor implicitly. Applicant is asked to either 1) clearly point out where in the original Disclosure this information can be found, or 2) delete the New Matter in order to overcome this rejection.

Claim Rejections - 35 USC § 103

Claims 1, 9-13 and 17-24 remain rejected and claims 28-30 (new) are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal (US 6,290,996 B1) in view of Dewhirst (US 4,563,526).

Applicant's arguments, as well as amendments to the claims were fully considered, but not found persuasive.

Applicant argues that Ghosal disclosed 5-15% of the flavonoid rutin, and therefore did not provide motivation for less than 1% by weight of flavonoids as currently claimed (pp.5- 6, Arguments). However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations of components because *concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art*. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature. One of ordinary skill in the art would have been motivated to have modified the proportions of active ingredients in the composition in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment. Such variations in amounts

of pharmaceutically active ingredients is considered merely optimization of result effective variables, conventional practice in the art of pharmacology.

Applicant further argues that Ghosal did not specifically teach the specific administration parameters as set forth in the Instant claims (p. 6, Arguments). It is noted that first, Applicant has amended claim 1 to read 'perorally' and not topically. Ghosal taught that the composition was to be administered orally (i.e., in the form of a capsule or tablet, col. 4, lines 19-23). It is deemed that the composition is so similar, that the composition would have intrinsically functioned within the manner as set forth in the preamble of the Instant claims; specifically 'retard, prevent and reverse the sign of skin photo-damage' because it is essentially the same composition being administered. As it has been keenly established in the previous Office Action, the administration of the extract would have been obvious to one of ordinary skill in the art, even with minor adjustments of concentration of constituents (i.e., flavonoids). It is deemed that administration of the composition disclosed by Ghosal at any time would have intrinsically performed the method as indicated by the claims because it is deemed that the terms 'effective dose is begun two to three days before sun exposure' and 'effective dose is begun a week before sun exposure' are very broad terms. Unless one lives in a dark-room they are subject to sun-exposure. Even if one does not go out of doors, most dwellings comprise windows which allows for sun exposure. It is deemed that one of ordinary skill in the art, after taking the composition disclosed by Ghosal, would have

Art Unit: 1655

been motivated to go outside on a sunny day everyday, including two or three days, or a week after taking the composition, in order to commute to work for example.

Applicant argues that ‘...secondary reference shows that on column 6 that the compounds set forth in the reference are indicated as prostaglandin synthetase inhibitors which are of potential value in treating thromboambolic disorders. It is not seen that the teachings of this reference indicate that the compound should be used topically for such a utility” (emphasis in the original, p. 7, Arguments). However, one of ordinary skill in the art would have been motivated to apply the composition of Ghosal topically to treat inflammation because it is clear from Dewhirst that compounds which inhibit platelet aggregation are useful for such a treatment. One of ordinary skill in the art would have had a reasonable expectation that because the composition disclosed by Ghosal inhibited platelet aggregation and because platelet aggregation plays a major role in inflammation, that topical administration of the composition disclosed by Ghosal would have had at least some effect in treating the inflammation topically especially absent convincing evidence to the contrary.

Secondly, it is noted that the only claims in the application that state ‘topically’ refer to the application of sunscreen. As it was noted in the previous rejection, the ordinary artisan would have been motivated to use sunscreen when taking the composition disclosed by Ghosal in order to avoid a sunburn. The use of sunscreen to prevent sunburn; and hence, damage to the skin is well known in the art. Claims 22-24

Art Unit: 1655

require the user to apply a sunscreen, however, the Examiner has provided reasons why the ordinary artisan would have been motivated to apply a sunscreen while taking the herbal supplement taught by Ghosal: The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant has submitted additional arguments with the letter filed on 4/15/05. Applicant indicated that col.12 of the reference states that rutin augments the extract. However, this information is not found in the reference (the Ghosal patent contains only 4 columns, wherein Applicant refers to column 12, further, the Examiner searched for this information but could not substantiate it).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 28-30 are free of the art.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached from 8:30am-5:00pm Monday – Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

7/5/05

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a long horizontal flourish extending to the right.